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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,409	06/26/2003	Peter Boileau	A03P1028	8460

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PACESETTER, INC.
15900 VALLEY VIEW COURT
SYLMAR, CA 91392-9221

EXAMINER	
MALAMUD, DEBORAH LESLIE	
ART UNIT	**PAPER NUMBER**
3766	

DATE MAILED: 01/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/608,409	BOILEAU ET AL.	
	Examiner	Art Unit	
	Deborah Malamud	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 June 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6-16,18 and 19* is/are rejected.

7)☒ Claim(s) *4,5 and 17* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 June 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/26/03,11/21/03,* 1/3/06
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-3, 6-8, 11-13 and 18-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Mehra et al (U.S. 2003/0144701). Mehra discloses (paragraph 0017) "the IMD reacts responsively addressing various needs in connection with administering anti-arrhythmic drugs to a patient to prevent and/or terminate atrial fibrillation while monitoring a patient's cardiac signals to predict and/or detect an onset of ventricular proarrhythmia. Drug therapy initiation/termination thresholds may be the same or different than thresholds established for the initiation/termination of pacing operations, and drug therapy termination thresholds may be different than drug therapy initiation thresholds. The IMD monitors routinely monitors cardiac signals for conditions including, but not limited to, Q-T interval prolongation, Q-T interval variability and a high frequency of ventricular ectopy as indicators that conditions exist for the onset of ventricular arrhythmia and that drug therapy should be terminated." Mehra further discloses (paragraph 0031) that the cardiac signals are monitored using an ECG that is either external to the patient or using an ECG recorder that is "an IMD recorder and

analyzer...According to a further example implementation, the functionality of pacing IMD (103) and IMD (110) are integrated into a single IMD package as indicated in FIG. 2 by dashed box (120)." The examiner considers this to be administering an anti-arrhythmic drug to a patient, receiving patient cardiac electrical signals via an implantable cardiac stimulation device implanted in the patient, analyzing the patient cardiac electrical signals and automatically controlling operation of the implantable cardiac stimulation device based on results of the analysis of the patient cardiac electrical signals.

Regarding claim 2, Mehra discloses a device that measures Q-T interval prolongation, Q-T interval variability and a high frequency of ventricular ectopy as indicators that conditions exist for the onset of ventricular arrhythmia. The examiner considers this to be analyzing event duration and event variability.

Regarding claim 3, Mehra discloses (paragraph 0030) "IMD measures at least one electrocardiogram characteristic indicative of an atrial fibrillation, thereby detecting an atrial arrhythmia of the heart, and thereafter transmitting a warning signal to patient." The examiner considers this to be outputting a warning signal if the efficacy of the antiarrhythmic drugs falls below a predetermined threshold.

Regarding claim 6, Mehra discloses (paragraph 0034) "IMD prevents delivery of drug therapy responsive to a determination that conditions are detected that are predictive of a possible onset of ventricular arrhythmia...IMD is adapted to prevent drug delivery from IMD drug pump (116) responsive to a determination by IMD that conditions are detected that are predictive of a possible onset of ventricular arrhythmia,

for example through comparison of a measured Q-T interval duration with a predetermined range for Q-T interval duration, drug therapy delivery being prevented responsive to the Q-T interval duration being out of range. IMD drug pump 116 is a stand-alone IMD, communicatively coupled to IMDs (103) and/or (110), or IMD package (120), in one example implementation." The examiner considers this to be a drug pump, wherein dosage of antiarrhythmic drugs delivered by the drug pump based on the results of the analysis of the patient cardiac electrical signals.

Regarding claim 7, Mehra discloses (paragraph 0007) "the heart is paced from within the patient at a predefined rate responsive to measuring the at least one electrocardiogram characteristic. Pacing may occur alone, or in combination with drug therapy delivery." The examiner considers this to teach an implantable cardiac stimulation device capable of performing cardiac pacing, and controlling cardiac pacing based on the results of the analysis of the patient cardiac electrical signals.

Regarding claim 8, Mehra discloses (paragraph 0015) "IMD automatically initiates ventricular overdrive pacing in an attempt to prevent ventricular proarrhythmia responsive to the comparisons." The examiner considers this to teach an implantable cardiac stimulation device capable of performing dynamic overdrive pacing and controlling an aggressiveness of overdrive pacing based on the results of the analysis of the patient cardiac electrical signals.

Regarding claims 11 and 12, Mehra discloses (paragraph 0033) "IMD is adapted to determine that conditions predictive of a possible onset of ventricular arrhythmia exist whenever measured Q-T interval durations exceed the predetermined duration limits."

The examiner considers this to be inputting values representative of expected changes of features of cardiac electrical signals and comparing features of patient cardiac electrical signals detected before administration of the drug to verify that the expected changes occur. The examiner also considers these predetermined duration limits to be templates representative of expected quantitative features of cardiac electrical signals.

Regarding claim 13, the examiner considers an IMD that generates data in forms including "Q-T prolongation data, Q-T interval variability data and ventricular ectopy data" to represent inputting templates representative of expected qualitative changes of features of cardiac electrical signals.

Regarding claim 18, the examiner considers IMD drug pump 116 in Figure 2 to be means for administering antiarrhythmic drugs to the patient, IMD ECG recorder and analyzer 110 to be means for receiving patient cardiac electrical signals and analyzing the patient cardiac electrical signals, and the fact that "the IMD monitors routinely monitors cardiac signals for conditions including, but not limited to, Q-T interval prolongation, Q-T interval variability and a high frequency of ventricular ectopy as indicators that conditions exist for the onset of ventricular arrhythmia and that drug therapy should be terminated" teaches a means for controlling operation of the implantable cardiac stimulation device based on the results of the analysis of the patient cardiac electrical signals.

Regarding claim 19, in view of the structure as disclosed by Mehra, the method of operating or using the device would be inherent because it is the normal and logical means by which the device can be used.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mehra et al (U.S. 2003/0144701) in view of Ideker et al (U.S. 2003/0153951). Mehra discloses the claimed invention except for an implantable cardiac stimulation device capable of performing defibrillation functions and controlling defibrillation functions based on the results of the analysis of the patient cardiac electrical signals. Ideker however discloses (paragraph 0059) "the electronic circuit (115) also includes a cardiac cycle monitor ("synchronization monitor 172") for providing synchronization information to the controller (174). As discussed below, the synchronization is typically provided by sensing cardiac activity in the RV, but may also include other sensing electrodes which can be combined with the defibrillation electrodes or employed separately to provide additional assurance that defibrillation shock pulses are not delivered during sensitive portions of the cardiac cycle so as to reduce the possibility of inducing ventricular fibrillation." Mehra and Ideker both disclose methods of combination stimulation and drug therapy to treat arrhythmias. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Mehra's arrhythmia system

with Ideker's defibrillation function in order to treat a fibrillation that occurs during pacing and drug therapy.

Regarding claim 10, Mehra discloses (paragraph 0043) "The defibrillation electrodes may alternately be configured to sense cardiac cycles, or may have smaller sensing electrodes placed adjacent thereto and thereby provide input to the electronics package as well as provide a predetermined stimulation shock output to predetermined cardiac areas as directed by the controller. The controller may also direct the amount of calcium control blocker, calmodulin blocker, calmodulin kinase inhibitor or antiarrhythmic drug to be inserted into a subject based upon the occurrence of an arrhythmia." The examiner considers this to be a sensor for sensing a physiological parameter affected by anti-arrhythmia drugs, and inputting physiological signals from the sensor and analyzing the signals to corroborate the results of the analysis of the patient cardiac electrical signals.

5. Claims 14 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mehra et al (U.S. 2003/0144701). Mehra discloses the claimed invention but does not disclose expressly the use of patient cardiac electrical signals detected at the same time of day. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the anti-arrhythmia system as taught by Mehra, with the analysis of signals at a certain time of day, because the applicant has not disclosed that it provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the applicant's invention to perform equally well with the time period as taught by Mehra, because

Mehra's system measures cardiac signals and determines what combination of drug and stimulation therapy to administer. Therefore, it would have been an obvious matter of design choice to modify Mehra's anti-arrhythmia system to obtain the invention as specified in the claims.

Regarding claim 16, Mehra discloses the claimed invention but does not disclose expressly the step of tracking RT intervals affected by antiarrhythmic drugs. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the method of terminating atrial arrhythmia using comparison of QT intervals as taught by Mehra, with the tracking of RT intervals, because the applicant has not disclosed the tracking of RT intervals provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the applicant's invention to perform equally well with the QT interval analysis as taught by Mehra, because Mehra teaches analysis of waveforms from ECG and modification of treatment based on this analysis. Therefore, it would have been an obvious matter of design choice to modify Mehra's QT analysis to obtain the invention as specified in the claims.

6. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mehra et al (U.S. 2003/0144701) in view of Zhou et al (U.S. 2004/0064062). Mehra discloses the claimed invention except for analyzing patient cardiac electrical signals using only averaged patient cardiac electrical signals. Zhou however discloses (paragraph 0054) "a template of the EGM signal may be digitized and stored (at step 490). The template may be taken from one cardiac cycle during a non-sustained arrhythmia episode or an

average of the EGM signal sampled over a given number of cardiac cycles during a non-sustained arrhythmia episode." Mehra and Zhou both disclose detection of arrhythmia and adjustment of detection of arrhythmia. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Mehra's anti-arrhythmia treatment system with Zhou's arrhythmia detection system in order to gain patient information to better diagnose and treat arrhythmia.

Allowable Subject Matter

7. Claims 4-5 and 17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. 5,925,066 to Kroll et al, disclosing Atrial arrhythmia sensor with drug and electrical therapy control apparatus

U.S. 5,474,574 to Payne et al, disclosing Automatic external cardioverter/defibrillator

U.S. 2005/0033368 to Fishler et al, disclosing Implantable cardiac device for and method of monitoring progression or regression of heart disease by quantifying morphological features

U.S. 6,941,168 to Girouard, disclosing System and method for treating an adverse cardiac condition using combined pacing and drug delivery

U.S. 5,405,362 to Kramer et al, disclosing Interactive external defibrillation and drug injection system

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Malamud whose telephone number is (571) 272-2106. The examiner can normally be reached on Monday-Friday, 8.00am-5.30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571)272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert E Pezzuto
Supervisory Patent Examiner
Art Unit 3766

Deborah L. Malamud
Patent Examiner
Art Unit 3766